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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CARTER, KENDRA D	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/758,417	BURNSIDE ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-57* is/are rejected.

7)☒ Claim(s) *57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/15/07,2/9/07,10/11/06,3/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 57 is dependent on 52, which is dependent on 41. Claims 41 and 57 state the same limitation of comprising a protective coating layer.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(1) Claims 1-17 and 19-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 and 21-24 of U.S. Patent No. 6,322,819 B1 ('819) in view of Deutsch (US 3,066,075), and in further view of Mulye (US 6,475,493 B1).

Although the conflicting claims are not identical, they are not patentably distinct from each other.

The patent '819 teaches a pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts comprising: (a) one or more amphetamine salts covered with an immediate release coating; and (b) one or more amphetamine salts covered with an enteric release coating that provides for delayed pulsed enteric release (see claims 1, 8, 13 and 18). The enteric release coating has a thickness of at least 25μ (see claim 2). The amphetamine salts can be coated onto a core or incorporation into a core (see claims 3, 4, 9, 10, 14, 15, 21 and 22). The amphetamine salts can be coated with an immediate release coating and an enteric release coating on a single core or on different cores (see claims 5, 11, 12, 16, 17, 23 and 24). The enteric release coating can be a non-pH dependent (see claim 7). A composition further comprises a protective layer over the enteric release coating or a

protective layer between the amphetamine salt and the enteric release coating (see claims 13 and 18).

The patent '819 does not teach the specific amphetamine salts dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate, or the dosage amounts. A pharmaceutically acceptable carrier, an anionic copolymer based on methacrylic acid and acrylic acid ethyl ester, properties, dosage amounts, or method of treatment of the composition as disclosed in claims 19, 20, 28-32, 36-39, 42, 43, 46-53 are not taught. The patent '819 also does not teach a second layer surrounding the first layer and the first layer surrounding the core, or wherein the amphetamine salts are provided in about the same amounts.

Deutsch teaches a therapeutic composition in a time-released form such as to give immediate effect and to be released for effectiveness either more or less continuously or at intervals over an extended period of time, e.g. 8 hours or so (see column 1, lines 12, 14, 15, and 19-22). The drug employed is *d* (i.e. dextro), *l* and *dl*-forms of amphetamine in the form of its salts, such as succinate, tartrate, citrate and sulfate salts in an admixture (see column 1, lines 40-43 and column 2, lines 11-15; addresses claims 6, 10, 41 and 57). The time-released form is either in a suspension of enteric coated pellets containing the ingredients of the composition in a solution such as water, with or without ethanol or glycerol or a system comprising the composition

dissolved form for immediate release and as the second release the composition suspended in oily material with is not digested for about 6-8 hours (see column 3, lines 54-67). The tablets may have 2 or more layers to give maximum psychological effect (see column 3, lines 69 and 70-71 and column 5, lines 21-40).

Mulye teaches a coated pharmaceutical formulation that provides a release of medicaments in a controlled manner comprising a coating surrounding a core element, a water insoluble polymer which is pH independent and an enteric polymer which is insoluble in water at a pH below 4.5 and soluble at a pH between above about 6.0 (see abstract lines 4, 5, 14 and column 4, lines 39-42 and 44-48). Insoluble polymers include acrylic and/or methacrylic ester polymers, polymers of copolymers of acrylates or methacrylates including EUDRAGIT RS and EUDRAGIT RL (i.e. anionic copolymer based on methacrylic acid and acrylic acid ethyl ester, see column 5, lines 51-56 and 61). A typical active ingredient is amphetamine sulfate (see column 9, line 43), which is present in amounts of approximately 0.1 to 95% by weight, based on the total weight of the core element (see column 10, lines 47-49; addresses dosage amounts).

In regards to the method of treatment of the composition, these factors are not considered in composition claims. The claims are only treated on the merits as related to a composition. Also, in regards to the properties of the composition, they are inherent to the composition because where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by

identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). This applies to all further rejections.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '819 and the specific amphetamine salts dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate or wherein the amphetamine salts are provided in about the same amounts, and its dosage amount because they are species of the genus amphetamine salts. Without unexpected results, the above amphetamine salts should perform the same as the genus. Additionally, Deutsch teaches a controlled release composition comprising *d* (i.e. dextro), *l* and *dl*- forms of amphetamine in the form of its salts, such as succinate, tartrate, citrate and sulfate salts in an admixture (see column 1, lines 40-43 and column 2, lines 11-15). It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994);

In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '819 and a pharmaceutically acceptable carrier, an anionic copolymer based on methacrylic acid and acrylic acid ethyl ester, or a second layer surrounding the first layer and the first layer surrounding the core (claim 26), because (1) Deutsch teaches a time-released composition either in a suspension of enteric coated pellets containing the ingredients of the composition in a solution such as water, with or without ethanol or glycerol or a system comprising the composition dissolved form for immediate release and as the second release the composition suspended in oily material with is not digested for about 6-8 hours (see column 3, lines 54-67); (2) the tablets may have 2 or more layers to give maximum psychological effect (see column 3, lines 69 and 70-71 and column 5, lines 21-40); and (3) Mulye teaches a coated pharmaceutical formulation comprising amphetamine sulfate (see column 9, line 43) that provides a controlled release further comprising a coating surrounding a core element, a water insoluble polymer which is pH independent and an enteric polymer which is insoluble in water at a pH below 4.5 and soluble at a pH between above about 6.0 (see abstract lines 4, 5, 14 and column 4, lines 39-42 and 44-48). Insoluble polymers include acrylic and/or methacrylic ester polymers, polymers of copolymers of acrylates or methacrylates including EUDRAGIT RS and EUDRAGIT RL (i.e. anionic

copolymer based on methacrylic acid and acrylic acid ethyl ester, see column 5, lines 51-56 and 61). The patent '819, Deutsch, and Mulye compositions are controlled release compositions. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

(2) Claims 1-4, 6-13, 15-17, 19-24, 26, 28-32, 34-44, 46-54, 56 and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10-14 of U.S. Patent No. 6,605,300 B1 ('300) in view of Mulye (US 6,475,493 B1).

Although the conflicting claims are not identical, they are not patentably distinct from each other.

The patent '300 teaches a pharmaceutical formulation for delivery of a mixture of amphetamine base salts effective to treat ADHD comprising an immediate release dosage form; a delayed enteric release dosage that provides delayed release upon oral administration; and a pharmaceutically acceptable carrier; wherein said amphetamine base salts comprise dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate containing about a total dose of 20 mg (see claims 1 and 12). The enteric release dosage form comprises a coating of a thickness of at least 20 μm or 25 μm (see claims 10, 11 and 13). The formulation further comprises an anionic copolymer (see claim 14).

The formulation of '300 does not teach the properties of the composition, a delayed release that is pH independent, or a protective layer. Also, the amphetamine salts coated onto a core or incorporated into a core, or wherein the immediate release and enteric release portions are present on a single core is not taught. Lastly, the amphetamine salts provided in about equal amounts is not taught.

Mulye teaches a coated pharmaceutical formulation that provides a release of medicaments in a controlled manner comprising a coating surrounding a core element, a water insoluble polymer which is pH independent and an enteric polymer which is insoluble in water at a pH below 4.5 and soluble at a pH between above about 6.0 (see abstract lines 4, 5, 14 and column 4, lines 39-42 and 44-48). A typical active ingredient is amphetamine sulfate (see column 9, line 43). The composition can contain two

coats. The coat immediately surrounding the central core comprises the soluble polymer, the combination of the insoluble polymer and the enteric polymer are coated around the first coat layer and forms a second coat layer (see column 7, lines 44-52). The active ingredient is contained in the core element (see column 10, lines 52 and 53). After coating, the pharmaceutical composition may be subjected to a sugar coating or additional coatings using another coating agent, which meets the limitation of a protective coating layer (see column 13, lines 65-67 to column 14, line 1).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '300 and a delayed release that is pH independent, a protective layer, wherein the amphetamine salts coated onto a core or incorporated into a core, or wherein the immediate release and enteric release portions are present because Mulye teaches a controlled release composition that comprises a pH independent delayed release component see abstract lines 4, 5, 14), a protective layer (see column 13, lines 65-67 to column 14, line 1), a multiple coat composition wherein the coat immediately surrounding the amphetamine salt central core comprises the soluble polymer, the combination of the insoluble polymer and the enteric polymer are coated around the first coat layer and forms a second coat layer (see column 7, lines 44-52; column 9, line 43; and column 10, lines 52 and 53).

The patent '300 and Mulye compositions are controlled release compositions. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

(3) Claims 1-5 and 15-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9, 11, 12, 14-17, 19, 21, 23, 24, 29 and 35-37 of U.S. Patent No. 6,913,768 B2 ('768) in view of Deutsch (US 3,066,075).

Although the conflicting claims are not identical, they are not patentably distinct from each other.

The patent '768 teaches a pharmaceutical composition comprising a mixture of amphetamine salts and a sustained release coating or matrix for a 20 mg total dose (see claims 1, 7, 11, 12, 14, 15, 24, 31, and 35). The composition specifically comprises a mixture of dextroamphetamine sulfate, dextroamphetamine succharate,

amphetamine aspirate monohydrate or amphetamine sulfate and also in equal amounts by weight (see claims 2, 3, 19, and 36). The amphetamine salts are provided in a core which is coated with a dissolution regulating agent that provides sustained release (see claims 4, 5, 17, 21, 23, 24, and 29). The sustained release coating or matrix has a pH independent dissolution release (see claim 31).

The patent '768 does not teach the properties of the composition, an immediate release coating, or an enteric release coating with a thickness of at least 25μ.

Deutsch teaches a therapeutic composition in a time-released form such as to give immediate effect and to be released for effectiveness either more or less continuously or at intervals over an extended period of time, e.g. 8 hours or so (see column 1, lines 12, 14, 15, and 19-22). The drug employed is *d* (i.e. dextro), *l* and *dl*-forms of amphetamine in the form of its salts, such as succinate, tartrate, citrate and sulfate salts in an admixture (see column 1, lines 40-43 and column 2, lines 11-15). The time-released form is either in a suspension of enteric coated pellets containing the ingredients of the composition in a solution such as water, with or without ethanol or glycerol or a system comprising the composition dissolved form for immediate release and as the second release the composition suspended in oily material with is not digested for about 6-8 hours (see column 3, lines 54-67). The tablets may have 2 or more layers to give maximum psychological effect (see column 3, lines 69 and 70-71 and column 5, lines 21-40). The thickness of the enteric coated pellets are adjusted to

be dissolved or digested in the body in about 3.5 (i.e. immediate release coating) and 7 hours (see column 4, lines 54-57 and 62-65).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '768 and an immediate release coating and an enteric release coating with a thickness of at least 25μ because Deutsch teaches an amphetamine salt time-released composition in a suspension of enteric coated pellets, wherein the thickness of the enteric coated pellets are adjusted to be dissolved or digested in the body in about 3.5 (i.e. immediate release coating) and 7 hours (see column 4, lines 54-57 and 62-65). Thus, the thickness of the enteric coated pellet can be adjusted by one skilled in the art to achieve the desired dissolution properties. It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

The patent '768 and Deutsch compositions are controlled release compositions. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from

their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

(4) Claims 1-4, 6-13, 15-17, 19-26, 28-44, 46-54, 56 and 57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/091,010 ('010) in view of Mulye (US 6,475,493 B1).

This is a provisional obviousness-type double patenting rejection.

The application '010 teaches a pharmaceutical formulation for delivery of a mixture of amphetamine base salts effective to treat ADHD comprising an immediate release dosage form; a delayed enteric release dosage that provides delayed release upon oral administration; and a pharmaceutically acceptable carrier; wherein said amphetamine base salts comprise dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate containing about a total dose of 20 mg (see claim 1). The enteric release dosage form comprises a coating of a thickness of at least 20 μm or 25 μm (see claims 10-13) and the salts are contained in about equal amounts within each of said dosage forms (see claim 9). The

formulation further comprises an anionic copolymer (see claims 10, 12 and 14). The coating is soluble at a pH of about 5.5 upwards (see claims 10 and 12). The formulation maintains an effective level of amphetamine salts in the patient over the course of at least 8 hours without further administration and the peak plasma concentration reached after release of said delayed enteric release dosage form exceeds the peak plasma concentration previously reached after release of said immediate release dosage form (see claim 1). The dosage amounts are 20 mg to produce a plasma concentration versus time curve having an area under the curve (AUC) of about 467 to about 714 ng hr/ml, and a maximum concentration (C_{max}) of about 22.5 to about 40 ng/ml for about 7 to about 10 hours (see claims 1-8 and 15-17). The composition is formulated such that the total amphetamine dose having an AUC proportional to the AUC of a composition formulated for a 20 mg total amphetamine dose, and having a C_{max} proportional to the C_{max} for a 20 mg total amphetamine dose (see claims 17 and 18). The delayed release is pH independent and the composition further comprises a protective coating layer (see claims 19 and 20).

The application '010 does not teach the amphetamine salts coated onto a core or incorporated into a core, or wherein the immediate release and enteric release portions are present on a single core.

Mulye teaches a coated pharmaceutical formulation that provides a release of medicaments in a controlled manner comprising a coating surrounding a core element,

a water insoluble polymer which is pH independent and an enteric polymer which is insoluble in water at a pH below 4.5 and soluble at a pH between above about 6.0 (see abstract lines 4, 5, 14 and column 4, lines 39-42 and 44-48). A typical active ingredient is amphetamine sulfate (see column 9, line 43). The composition can contain two coats. The coat immediately surrounding the central core comprises the soluble polymer, the combination of the insoluble polymer and the enteric polymer are coated around the first coat layer and forms a second coat layer (see column 7, lines 44-52). The active ingredient is contained in the core element (see column 10, lines 52 and 53).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '010 and wherein the amphetamine salts coated onto a core or incorporated into a core, or wherein the immediate release and enteric release portions are present because Mulye teaches a controlled release composition that comprises a multiple coat composition wherein the coat immediately surrounding the amphetamine salt central core comprises the soluble polymer, the combination of the insoluble polymer and the enteric polymer are coated around the first coat layer and forms a second coat layer (see column 7, lines 44-52; column 9, line 43; and column 10, lines 52 and 53).

The application '010 and Mulye compositions are controlled release compositions. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third

composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

(5) Claims 1-17 and 19-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-18 21-24 and 26 of copending Application No. 11/091,011 ('011) in view of Deutsch (US 3,066,075), and in further view of Mulye (US 6,475,493 B1).

This is a provisional obviousness-type double patenting rejection.

The application '011 teaches a pharmaceutical formulation for delivery of a mixture of amphetamine base salts comprising an immediate release dosage form; and a delayed enteric release dosage that provides delayed release upon oral administration wherein the enteric release dosage form comprises a coating of a thickness of at least 25 μm (see claims 1, 2, 5, 8, 11, 13, and 18). The amphetamine salts are coated onto a core or incorporated into a core (see claims 3, 4, 14, and 15) The amphetamine salts are covered with an enteric release coating on a single core or covered with an immediate release coating on one core and amphetamine salt covered

with an enteric release coating on a different core (see claims 5, 6, 11, 12, 16, 17, 21, 22, 23 and 24). The delayed pulse enteric release of amphetamine salt increases the blood level of amphetamine salt to a second level that is greater than the first level provided by the component (see claims 8 and 11). The formulation further comprises a protective layer over the enteric release coating (see claim 13).

The application '011 does not teach the specific amphetamine salts dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate and its dosage amount. A pharmaceutically acceptable carrier, an anionic copolymer based on methacrylic acid and acrylic acid ethyl ester, properties, dosage amounts, or method of treatment of the composition as disclosed in claims 19, 20, 28-32, 36-39, 42, 43, 46-53 are not taught. The application '010 also does not teach a second layer surrounding the first layer and the first layer surrounding the core, or wherein the amphetamine salts are provided in about the same amounts.

Deutsch teaches a therapeutic composition in a time-released form such as to give immediate effect and to be released for effectiveness either more or less continuously or at intervals over an extended period of time, e.g. 8 hours or so (see column 1, lines 12, 14, 15, and 19-22). The drug employed is *d* (i.e. dextro), *l* and *dl*-forms of amphetamine in the form of its salts, such as succinate, tartrate, citrate and sulfate salts in an admixture (see column 1, lines 40-43 and column 2, lines 11-15;

addresses claims 6, 10, 41 and 57). The time-released form is either in a suspension of enteric coated pellets containing the ingredients of the composition in a solution such as water, with or without ethanol or glycerol or a system comprising the composition dissolved form for immediate release and as the second release the composition suspended in oily material with is not digested for about 6-8 hours (see column 3, lines 54-67). The tablets may have 2 or more layers to give maximum psychological effect (see column 3, lines 69 and 70-71 and column 5, lines 21-40).

Mulye teaches a coated pharmaceutical formulation that provides a release of medicaments in a controlled manner comprising a coating surrounding a core element, a water insoluble polymer which is pH independent and an enteric polymer which is insoluble in water at a pH below 4.5 and soluble at a pH between above about 6.0 (see abstract lines 4, 5, 14 and column 4, lines 39-42 and 44-48). Insoluble polymers include acrylic and/or methacrylic ester polymers, polymers of copolymers of acrylates or methacrylates including EUDRAGIT RS and EUDRAGIT RL (i.e. anionic copolymer based on methacrylic acid and acrylic acid ethyl ester, see column 5, lines 51-56 and 61). A typical active ingredient is amphetamine sulfate (see column 9, line 43), which is present in amounts of approximately 0.1 to 95% by weight, based on the total weight of the core element (see column 10, lines 47-49; addresses dosage amounts).

In regards to the method of treatment of the composition, these factors are not considered in composition claims. The claims are only treated on the merits as related

to a composition. Also, in regards to the properties of the composition, they are inherent to the composition because where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). This applies to all further rejections.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '011 and the specific amphetamine salts dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate or wherein the amphetamine salts are provided in about the same amounts, and its dosage amount because they are species of the genus amphetamine salts. Without unexpected results, the above amphetamine salts should perform the same as the genus. Additionally, Deutsch teaches a controlled release composition comprising *d* (i.e. dextro), *l* and *dl*- forms of amphetamine in the form of its salts, such as succinate, tartrate, citrate and sulfate salts in an admixture (see column 1, lines 40-43 and column 2, lines 11-15). It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an

optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '011 and a pharmaceutically acceptable carrier, an anionic copolymer based on methacrylic acid and acrylic acid ethyl ester, or a second layer surrounding the first layer and the first layer surrounding the core (claim 26), because (1) Deutsch teaches a time-released composition either in a suspension of enteric coated pellets containing the ingredients of the composition in a solution such as water, with or without ethanol or glycerol or a system comprising the composition dissolved form for immediate release and as the second release the composition suspended in oily material with is not digested for about 6-8 hours (see column 3, lines 54-67); (2) the tablets may have 2 or more layers to give maximum psychological effect (see column 3, lines 69 and 70-71 and column 5, lines 21-40); and (3) Mulye teaches a coated pharmaceutical formulation comprising amphetamine sulfate (see column 9, line 43) that provides a controlled release further comprising a coating surrounding a core element, a water insoluble polymer which is pH independent and an enteric polymer which is insoluble in water at a pH below 4.5 and soluble at a pH between above about 6.0 (see abstract lines 4, 5, 14 and column 4, lines 39-42 and 44-48). Insoluble

polymers include acrylic and/or methacrylic ester polymers, polymers of copolymers of acrylates or methacrylates including EUDRAGIT RS and EUDRAGIT RL (i.e. anionic copolymer based on methacrylic acid and acrylic acid ethyl ester, see column 5, lines 51-56 and 61). The application '010, Deutsch, and Mulye compositions are controlled release compositions. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

(6) Claims 1-4, 6-13, 15-17, 19-26, 28-44, 46-54, 56 and 57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5-7 of copending Application No. 11/443,151 ('151) in view Mulye (US 6,475,493 B1).

This is a provisional obviousness-type double patenting rejection.

The application '151 teaches a pharmaceutical formulation for delivery of a mixture of amphetamine base salts effective to treat ADHD comprising an immediate

release dosage form; a delayed enteric release dosage that provides delayed release upon oral administration; and a pharmaceutically acceptable carrier; wherein the composition is sufficient to maintain an effective level of amphetamine base salts in the patient over the course of at least 8 hours without further administration of amphetamine base salt for about a 20 mg total dose, and the peak plasma concentration of amphetamine base salts reached after release of said delayed enteric release dosage form exceeds the peak plasma concentration previously reached after release of said immediate release dosage form (see claim 1). The enteric release dosage form comprises a coating of a thickness of at least 20 μm or 25 μm (see claims 6 and 7) and the salts are contained in about equal amounts within each of said dosage forms (see claim 5). The formulation further comprises an anionic copolymer and the coating is soluble at a pH of about 5.5 upwards (see claim 6).

The application '151 does not teach the specific amphetamine salts dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate. Also, the amphetamine salts coated onto a core or incorporated into a core, or wherein the immediate release and enteric release portions are present on a single core is not taught. Lastly, the properties of the composition and a protective layer is not taught.

Mulye teaches a coated pharmaceutical formulation that provides a release of medicaments in a controlled manner comprising a coating surrounding a core element,

a water insoluble polymer which is pH independent and an enteric polymer which is insoluble in water at a pH below 4.5 and soluble at a pH between above about 6.0 (see abstract lines 4, 5, 14 and column 4, lines 39-42 and 44-48). A typical active ingredient is amphetamine sulfate (see column 9, line 43). The composition can contain two coats. The coat immediately surrounding the central core comprises the soluble polymer, the combination of the insoluble polymer and the enteric polymer are coated around the first coat layer and forms a second coat layer (see column 7, lines 44-52). The active ingredient is contained in the core element (see column 10, lines 52 and 53). After coating, the pharmaceutical composition may be subjected to a sugar coating or additional coatings using another coating agent, which meets the limitation of a protective coating layer (see column 13, lines 65-67 to column 14, line 1).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '151 and the specific amphetamine salts dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate or wherein the amphetamine salts are provided in about the same amounts because they are species of the genus amphetamine salts. Without unexpected results, the above amphetamine salts should perform the same as the genus.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '151 and a protective layer, the amphetamine salts coated onto a

core or incorporated into a core, or the immediate release and enteric release portions are present because Mulye teaches the following: (1) a controlled release composition that comprises a multiple coat composition wherein the coat immediately surrounding the amphetamine salt central core comprises the soluble polymer, the combination of the insoluble polymer and the enteric polymer are coated around the first coat layer and forms a second coat layer (see column 7, lines 44-52; column 9, line 43; and column 10, lines 52 and 53); and (2) after coating, the pharmaceutical composition may be subjected to a sugar coating or additional coatings using another coating agent, which meets the limitation of a protective coating layer (see column 13, lines 65-67 to column 14, line 1).

The application '151 and Mulye compositions are controlled release compositions. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

(7) Claims 1-5 and 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-10, 23, 24, 28 and 31-39 of copending Application No. 11/030,174 ('174) in view of Deutsch (US 3,066,075).

This is a provisional obviousness-type double patenting rejection.

The application '174 teaches a pharmaceutical formulation comprising a sustained release formulation of at least one amphetamine salt which provides a mean plasma concentration profile in human ADHD patients, wherein at least one amphetamine or amphetamine salt is a mixture of dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate (see claims 6-8, 23, and 31). The amphetamine salts or mixtures thereof is 20 mg (see claim 28). The salts are administered in equal amounts (see claim 8) and are provided in a core, which is coated with a coating comprising a pharmaceutically acceptable water-insoluble polymer providing sustained release (see claims 9, 33 and 35). The coating further comprises a dissolution regulated agent (i.e. enteric release coating; see claim 10 and 34). The sustained release component is selected from water-soluble polymers, water-insoluble polymers, entero-soluble polymers, and mixtures thereof (see claim 34). The amphetamine component and sustained release component applied form at least one layer around the core (see claim 36), wherein at least one layer comprise a combination of at least one amphetamine component and at

least one sustained release component (see claim 37); or wherein each layer is individually comprised of amphetamine components or sustained release components (see claim 38); or wherein alternating layers of amphetamine components and sustained release components are applied to the core (see claim 39).

The application '174 does not specifically teach the properties of the composition, an immediate release coating or the thickness of the enteric release coating of at least 25μ.

Deutsch teaches a therapeutic composition in a time-released form such as to give immediate effect and to be released for effectiveness either more or less continuously or at intervals over an extended period of time, e.g. 8 hours or so (see column 1, lines 12, 14, 15, and 19-22). The drug employed is *d* (i.e. dextro), *l* and *dl*-forms of amphetamine in the form of its salts, such as succinate, tartrate, citrate and sulfate salts in an admixture (see column 1, lines 40-43 and column 2, lines 11-15). The time-released form is either in a suspension of enteric coated pellets containing the ingredients of the composition in a solution such as water, with or without ethanol or glycerol or a system comprising the composition dissolved form for immediate release and as the second release the composition suspended in oily material with is not digested for about 6-8 hours (see column 3, lines 54-67). The tablets may have 2 or more layers to give maximum psychological effect (see column 3, lines 69 and 70-71 and column 5, lines 21-40). The thickness of the enteric coated pellets are adjusted to

be dissolved or digested in the body in about 3.5 (i.e. immediate release coating) and 7 hours (see column 4, lines 54-57 and 62-65).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '174 and an immediate release coating and an enteric release coating with a thickness of at least 25μ because Deutsch teaches an amphetamine salt time-released composition in a suspension of enteric coated pellets, wherein the thickness of the enteric coated pellets are adjusted to be dissolved or digested in the body in about 3.5 (i.e. immediate release coating) and 7 hours (see column 4, lines 54-57 and 62-65). Thus, the thickness of the enteric coated pellet can be adjusted by one skilled in the art to achieve the desired dissolution properties. It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

The application '174 and Deutsch compositions are controlled release compositions. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them

flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

(8) Claims 1-4 and 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12, 14, 23 and 24 of copending Application No. 11/774,697 ('697) in view Mulye (US 6,475,493 B1).

This is a provisional obviousness-type double patenting rejection.

The application '697 teaches a pharmaceutical formulation for delivery of a mixture of amphetamine base salts (see claim 1) effective to treat ADHD (see claim 16) comprising an immediate release dosage form and a sustained or controlled release dosage form (see claim 23) an immediate release dosage form; wherein a single oral dosage provides amphetamine release in both said earlier and later periods (see claims 1 and 14). The total amphetamine dose per day is about 1 to about 200 mg (see claim 12).

The application '697 does not teach the specific amphetamine salts dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate. Neither a specific immediate release coating or enteric release coating is taught. Also, the amphetamine salts coated onto a core or incorporated into a core, or wherein the immediate release and enteric release portions are present on a single core is not taught. Lastly, the properties of the composition and the thickness of the enteric release coating is not taught.

Mulye teaches a coated pharmaceutical formulation that provides a release of medicaments in a controlled manner comprising a coating surrounding a core element, a water insoluble polymer which is pH independent and an enteric polymer which is insoluble in water at a pH below 4.5 and soluble at a pH between above about 6.0 (see abstract lines 4, 5, 14 and column 4, lines 39-42 and 44-48). A typical active ingredient is amphetamine sulfate (see column 9, line 43). The composition can contain two coats. The coat immediately surrounding the central core comprises the soluble polymer, the combination of the insoluble polymer and the enteric polymer are coated around the first coat layer and forms a second coat layer (see column 7, lines 44-52). The active ingredient is contained in the core element (see column 10, lines 52 and 53). For each drug, there is a predetermined or preferred release profile. The practitioner skilled in this art can easily determine the proper thickness of the coat to achieve this desired release profile (see column 14, lines 50-56).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '697 and the specific amphetamine salts dextroamphetamine sulfate, dextroamphetamine succharate, amphetamine aspirate monohydrate or amphetamine sulfate or wherein the amphetamine salts are provided in about the same amounts because they are species of the genus amphetamine salts. Without unexpected results, the above amphetamine salts should perform the same as the genus.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine '697 and a specific immediate release coating or enteric release coating, the thickness of the enteric release coating, the amphetamine salts coated onto a core or incorporated into a core, or the immediate release and enteric release portions are present because Mulye teaches the following: (1) a controlled release composition that comprises a multiple coat composition wherein the coat immediately surrounding the amphetamine salt central core comprises the soluble polymer, the combination of the insoluble polymer and the enteric polymer are coated around the first coat layer and forms a second coat layer (see column 7, lines 44-52; column 9, line 43; and column 10, lines 52 and 53); (2) after coating, the pharmaceutical composition may be subjected to a sugar coating or additional coatings using another coating agent, which meets the limitation of a protective coating layer (see column 13, lines 65-67 to column 14, line 1); and (3) a practitioner skilled in this art can easily determine the proper thickness of the

coat to achieve this desired release profile (see column 14, lines 50-56; addresses claims 1, 9, 16, 17, 34, 35 and 53).

The application '697 and Mulye compositions are controlled release compositions. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 and 19-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulye (US 6,475,493 B1) and further in view of Deutsch (US 3,066,075).

Mulye teaches a coated pharmaceutical formulation that provides a release of medicaments in a controlled manner comprising a coating surrounding a core element, a water insoluble polymer which is pH independent and an enteric polymer which is insoluble in water at a pH below 4.5 and soluble at a pH between above about 6.0 (see abstract lines 4, 5, 14 and column 4, lines 39-42 and 44-48; addresses claims 40, 53 and 56). Sustained release and controlled release are being used interchangeably and refer to the release of the active ingredient at such a rate that blood levels are maintained with a therapeutic range but below toxic levels over an extended period of time, e.g., 4 to 24 hours or even longer (see column 5, lines 14-19; addresses claims 19, 42 and 52). The insoluble polymer and the enteric polymer interact to form a barrier over the core element containing the active ingredient (see column 7, lines 9and 10; addresses claims 4, 13, 21, 44 and 54). Additionally, the composition can contain two coats. The coat immediately surrounding the central core comprises the soluble polymer, the combination of the insoluble polymer and the enteric polymer are coated around the first coat layer and forms a second coat layer (see column 7, lines 44-52; addresses claims 14, 22, 23, 24 and 26). Insoluble polymers include acrylic and/or methacrylic ester polymers, polymers of copolymers of acrylates or methacrylates including EUDRAGIT RS and EUDRAGIT RL (i.e. anionic copolymer based on

methacrylic acid and acrylic acid ethyl ester, see column 5, lines 51-56 and 61; addresses claim 53). The active ingredient is contained in the core element (see column 10, lines 52 and 53; addresses claims 3, 8 and 12). A typical active ingredient is amphetamine sulfate (see column 9, line 43; addresses claims 1, 6, 10, 15, 19 and 42), which is present in amounts of approximately 0.1 to 95% by weight, based on the total weight of the core element (see column 10, lines 47-49; addresses dosage amounts). The central core contains a lubricant such as hydrogenated vegetable oil and vegetable oil derivatives (see column 11, lines 20 and 21; addresses claims 19 and 42). Also, a suspension of the active ingredient is formed by dissolving or by dispersion of the active ingredient in distilled water (see column 12, lines 56-58; address claims 19 and 22). Although the above lubricants and distilled water are not labeled as pharmaceutical carriers, they are considered as such. "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The active ingredient contained in the core element can be provided in a solution or slurry then sprayed on a sugar or starch core seed (see column 12, line 5 and column13, lines 12-15; addresses claims 2, 7 and 11). After coating, the pharmaceutical composition may be subjected to a sugar coating or additional coatings using another coating agent, which meets the limitation of a protective coating layer (see column 13, lines 65-67 to column 14, line 1; addresses claims 6, 10, 41 and 57). Moreover the rate of release of the active component into the gastrointestinal tract can

be controlled by varying the thickness of the coating of the central core element. For each drug, there is a predetermined or preferred release profile. The practitioner skilled in this art can easily determine the proper thickness of the coat to achieve this desired release profile (see column 14, lines 50-56; addresses claims 1, 9, 16, 17, 34, 35 and 53).

Mulye does not teach any of the properties of the composition, dosage amounts, administration procedures or method of treatment disclosed in claims 15, 17, 20, 28-30, 36-39, 42, 43, 46-51 and 53. Also, the specific thickness of the enteric release coating and an immediate release form is not taught. Mulye additionally does not teach the immediate release and enteric release components being present on different cores (claims 5 and 13); the first layer comprising the amphetamine salt and at least one immediate release component and a second layer comprising an amphetamine salt and at least one delayed rapid release component (claims 25 and 27); the amphetamine salt covered with an immediate release coating and the amphetamine salt covered with an enteric release coating are present on different cores (claims 45 and 55); and the amphetamine salts are provided in about the same amounts (claims 33 and 52).

In regards to the method of treatment of the composition, these factors are not considered in composition claims. The claims are only treated on the merits as related to a composition. Also, in regards to the properties of the composition, they are inherent to the composition because where the claimed and prior art products are

identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Deutsch teaches a therapeutic composition in a time-released form such as to give immediate effect and to be released for effectiveness either more or less continuously or at intervals over an extended period of time, e.g. 8 hours or so (see column 1, lines 12, 14, 15, and 19-22; addresses claims 6, 10, 41 and 57). The drug employed is *d* (i.e. dextro), *l* and *dl*- forms of amphetamine in the form of its salts, such as succinate, tartrate, citrate and sulfate salts in an admixture (see column 1, lines 40-43 and column 2, lines 11-15; addresses claims 6, 10, 41 and 57). The time-released form is either in a suspension of enteric coated pellets containing the ingredients of the composition in a solution such as water, with or without ethanol or glycerol or a system comprising the composition dissolved form for immediate release and as the second release the composition suspended in oily material with is not digested for about 6-8 hours (see column 3, lines 54-67). The tablets may have 2 or more layers to give maximum psychological effect (see column 3, lines 69 and 70-71 and column 5, lines 21-40; addresses claims 5, 13, 25, 27, 45 and 55).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine a composition of Mulye and the specific thickness of the enteric release coating or the amount of the amphetamine salt in the formulation because Mulye teaches the following: (1) the rate of release of the active component into the gastrointestinal tract can be controlled by varying the thickness of the coating of the central core element; (2) amphetamine sulfate (see column 9, line 43) is present in amounts of approximately 0.1 to 95% by weight, based on the total weight of the core element (see column 10, lines 47-49); (3) for each drug, there is a predetermined or preferred release profile (see column 14, lines 50-56); and (4) the practitioner skilled in this art can easily determine the proper thickness of the coat to achieve this desired release profile (see column 14, lines 50-56). It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine a composition of Mulye and a specific immediate release form because of the following: (1) Mulye teaches a sustained release/controlled

release composition that releases of the active ingredient at such a rate that blood levels are maintained with a therapeutic range but below toxic levels over an extended period of time, e.g., 4 to 24 hours or even longer (see column 5, lines 14-19; addresses claims 19, 42 and 52); and (2) Deutsch teaches a therapeutic composition in a time-released form such as to give immediate effect and to be released for effectiveness either more or less continuously or at intervals over an extended period of time, e.g. 8 hours or so (see column 1, lines 12, 14, 15, and 19-22; addresses claims 6, 10, 41 and 57). Thus, in order to give an immediate effect, an immediate release coating can be employed, but for sustained/controlled release the enteric coating is employed. Both compositions provide for a controlled release composition. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

One of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine a composition of Mulye and the following: (1) the immediate release and enteric release components being present on different cores; (2) the first layer comprising the amphetamine salt and at least one immediate release

component and a second layer comprising an amphetamine salt and at least one delayed rapid release component; or (3) the amphetamine salt covered with an immediate release coating and the amphetamine salt covered with an enteric release coating are present on different cores, because Deutsch teaches a controlled release composition that has 2 or more layers to give maximum psychological effect (see column 3, lines 69 and 70-71 and column 5, lines 21-40). Thus, to achieve maximum psychological effect, one skilled in the art can layer the composition with the different components above with reasonable levels of expected success. This also applies to the amounts of amphetamine salts in the mixtures. Deutsch teaches that the amphetamine salts are in an admixture (see column 1, lines 40-43 and column 2, line 15). It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose

telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

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SUPERVISORY PATENT EXAMINER